

INSPECTOR GENERAL

Department of Defense

JULY 24, 2013



The TRICARE Mail Order Pharmacy Program Was Cost Efficient and Adequate Dispensing Controls Were in Place

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INSPECTOR GENERAL DEPARTMENT OF DEFENSE 4800 MARK CENTER DRIVE ALEXANDRIA, VIRGINIA 22350-1500

July 24, 2013

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: The TRICARE Mail Order Pharmacy Program Was Cost Efficient and Adequate Dispensing Controls Were in Place (Report No. DODIG-2013-108)

We are providing this report for your information and use. We performed this audit on the TRICARE Mail Order Pharmacy (TMOP) program (Project No. D2013-D000LF-0063) as requested by Congressional members from the Senate and the House of Representatives (see enclosures). Congressional members indicated that their overall concern was whether the TMOP program was providing prescription drugs in the most efficient and cost effective manner. In addition, the request included the following specific questions:

- Is higher utilization of mail order resulting in waste and increased health care costs?
- Are controls in place that ensure patients do not receive medications they no longer need?
- Do processes exist to halt shipments when a patient's physician changes the type of medication, dosage, strength, or other changes?
- Do beneficiaries have the opportunity to opt-out of automatic refill programs?

The objective of the audit was to determine the efficiency and effectiveness of selected aspects of the TMOP program. Specifically, we examined selected aspects of the TMOP program to address the Congressional questions. We determined it was generally more cost efficient for beneficiaries to obtain pharmaceuticals through the TMOP program than through retail pharmacies. In addition, adequate controls in the TMOP program over dispensing pharmaceuticals were in place.

Background

During FY 1994 and FY 1995, DoD conducted multiple concurrent demonstration projects to determine if a mail order pharmacy program would save money on prescription drug costs. Evaluation of the projects concluded that a nation-wide mail order program using federal pricing could result in savings. During this same period, DoD awarded the first TRICARE managed care support contracts. According to

TRICARE Management Activity (TMA), each contract included a mail order pharmacy benefit, but each contractor administered the benefit differently, leaving TMA with no visibility over effectiveness or cost. In 1997, DoD removed the mail order pharmacy responsibility from the managed care support contracts and awarded a National Mail Order Pharmacy contract. The National Mail Order Pharmacy contract included DoD's access to federal ceiling prices¹ and resulted in savings. Subsequently, DoD awarded the first TRICARE mail order contract to Express Scripts, Inc., in 2003. TMA administered the contract with Express Scripts, Inc., which resulted in reduced administrative costs.

In 2008, DoD awarded the TRICARE pharmacy contract to Express Scripts, Inc., which combined the TMOP program and the processing of TRICARE claims for retail pharmacy purchases. Contractor payment was based primarily on a flat administrative fee for each mail order prescription or retail claim processed and did not include the cost of obtaining the pharmaceuticals. The TMOP program allowed beneficiaries to receive up to a 90-day supply of medications for a single co-payment and was intended for maintenance medications—those medications taken on a regular basis. Although beneficiaries did not use mail order heavily before 2009, usage steadily increased from late 2009 through 2012, which TMA attributed in part to an aggressive communications plan. In a 2008 report, the Government Accountability Office concluded that DoD's efforts to encourage use of the TMOP program were important to limiting DoD's future prescription drug spending.² In FY 2012, TMA implemented modified pharmacy co-payments as established by public law, which resulted in lower out-of-pocket costs for beneficiaries using the TMOP program and higher costs for use of retail. This co-payment structure provided a 90-day supply of a generic medication at no cost to the beneficiary through the TMOP program compared to \$15 at a retail network pharmacy.

Beneficiaries have three options for enrolling in the TMOP program: mail a registration form with a new prescription, call the TMOP program contractor's toll-free number, or register on the TMOP program contractor's secure website. Once enrolled in the TMOP program, beneficiaries may add new prescriptions by mail, or by request to the prescriber to submit prescriptions by fax or electronically when permitted. Beneficiaries may order prescription refills by mailing the refill request form that they received with the previous shipment, by telephone, or through the TMOP program contractor's secure website. The TMOP program contractor also offers an optional automatic refill program. Shipping is provided at no cost to the beneficiary unless they request express or overnight delivery.

¹ Federal ceiling price is the maximum price that a manufacturer may charge DoD for certain drugs under Public Law 102-585; DoD must receive at least a 24 percent discount from the net wholesale price.

² GAO Report No. 08-327, "Continued Efforts Needed to Reduce Growth in Spending at Retail Pharmacies," April 2008.

The TRICARE Mail Order Program Was Cost Efficient and **Adequate Dispensing Controls Were in Place**

The aspects of the TMOP program examined were cost efficient relative to the retail pharmacy option. TMA's cost analysis showed that filling prescriptions through the TMOP program was generally more cost efficient than through retail pharmacies. Although some costs, such as waste and pharmaceuticals returned for destruction, were not included in the analysis, the effect was insignificant. In addition, adequate controls over dispensing pharmaceuticals through the TMOP program were in place based on our review and observation of dispensing operations, prescription error rates, pharmaceutical returns, and beneficiary satisfaction surveys. Overall, the TMOP program was more efficient and effective than retail programs, providing cost savings to DoD and potentially reducing health risks associated with dispensing incorrect pharmaceuticals.

Mail Order Efficiency Identified in Cost Analysis

TMA's cost analysis showed that the TMOP program cost 16.7 percent less than prescriptions obtained through retail pharmacies. TMA began monitoring efficiency with the mail order demonstrations projects that occurred during FY 1994 and FY 1995, and updated as needed to consider changes in the program. TMA currently performs a quarterly cost analysis that compares the costs of filling prescriptions at the three points of service during the quarter: TMOP program, military treatment facilities (MTF), and retail pharmacies. Examples of cost factors considered in the cost analysis include co-payments, pharmaceutical costs, contract administrative fees, claim processing fees, and retail rebates. We reviewed the methodology, cost factors, and computations in the third quarter FY 2012 analysis that showed that the TMOP program cost 16.7 percent less than the retail pharmacies. TMA's cost analysis was designed to consider "what if" scenarios. One of the TMA scenarios compared the cost of pharmaceuticals purchased through the TMOP program to what the cost would have been if purchased at retail pharmacies. Through this analysis for the third quarter FY 2012, TMA determined that \$398.9 million spent on mail order prescriptions would have cost \$465.7 million through retail pharmacies, resulting in about 16.7 percent savings. TMA's cost analysis also showed that generic pharmaceuticals generally cost DoD more through the TMOP program than through retail pharmacies. The co-payment exemption established by public law for generic pharmaceuticals offered through the TMOP program also contributed to this inefficiency. However, savings from brand name pharmaceuticals made the TMOP program more cost efficient overall. These conclusions were based on policies in effect as of third quarter FY 2012. Any significant program changes, such as modifying beneficiary co-payments or coverage, could affect the conclusions.

TMA limited the analysis to prescriptions for non-specialty maintenance pharmaceuticals, which included generic and brand name pharmaceuticals, because these prescriptions comprised the majority of prescriptions filled at all three points of service. At the time of our audit, TMA was developing a cost analysis for prescriptions for specialty pharmaceuticals³. TMA's cost analysis for prescriptions for non-specialty maintenance pharmaceuticals included cost factors such as: ingredient cost per unit, average prime vendor cost per unit, days' supply, quantity dispensed, dispensing fee, other contract costs, taxes, retail refunds, MTF overhead, and co-payments.

Not All Costs Were Considered

The TMA cost analysis did not include all of the costs associated with pharmaceutical dispensing. Specifically, the TMA cost analysis did not include contract costs that were indirectly associated with the cost of either mail order or retail prescriptions. For example, the analysis excluded the cost of returned pharmaceuticals that required disposal, which totaled 0.08 percent of the 16.9 million prescriptions dispensed during CY 2012. The costs of the returned pharmaceuticals were absorbed by both DoD and the TMOP program contractor. If the returned prescriptions were due to government error, such as a patient not listed as deceased in the Defense Eligibility Enrollment Reporting System⁴ (DEERS) at the time of shipment, the TMOP program contractor kept the administration fee it was paid at the time of the shipment. If the returned pharmaceuticals were due to TMOP program contractor error, such as shipping a pharmaceutical to the wrong patient, the administration fee was returned to TMA, the co-payment returned to the beneficiary, and the contractor absorbed the cost of the pharmaceutical. A company under contract with Defense Logistics Agency, Defense Supply Center Philadelphia would pick up returned pharmaceuticals and determine what is returnable to the manufacturer and what is waste. The effect of any of these excluded costs would not materially change TMA's cost analysis conclusions.

Waste Could Not Be Quantified

We did not identify information that quantified waste resulting from delivered, unneeded prescription medications. According to a pharmacy industry trade group, 15 percent of prescriptions from mail order pharmacy programs were associated with waste due to shipment of drugs that were no longer needed. Although we requested, the group did not provide specific information regarding waste related to the TMOP program. In

Specialty pharmaceuticals are high cost injectable, infused, oral, or inhaled drugs that are generally more complex to distribute, administer, and monitor.

⁴ DEERS is an automated information system designed to provide timely and accurate information on those eligible for DoD benefits and entitlements.

addition, we attempted to obtain information on waste from TMA and the TMOP program contractor, but they could not provide data related to this type of waste. However, the TMOP program contractor had designed and implemented dispensing controls to prevent shipment of unneeded or ineligible prescriptions, reducing the risk of waste.

We also did not find additional waste associated with dispensing a 90-day supply of pharmaceuticals through mail order than through retail pharmacies. A 2012 research study⁵ found that dispensing a 90-day supply of medication, whether by mail or at retail pharmacies, resulted in increased waste 57 percent of the time compared to a 30-day supply. Although TRICARE allowed beneficiaries up to a 90-day supply through the TMOP program, 90-day supplies were typical of other mail order prescription plans, which in 2012 were included in 93 percent of U.S. employers' drug benefit plans. Additionally, almost half of U.S. drug benefit plans included an option to allow 90-day supplies of maintenance medications at retail pharmacies.⁶ Like TRICARE, employer health plans offered reduced co-payments to incentivize use of mail order pharmacy programs. While dispensing a 90-day supply potentially resulted in increased waste compared to a 30-day supply, we found no reason to conclude that prescriptions dispensed through TMOP resulted in waste at higher rates than 90-day supplies from any other mail order or retail program.

Dispensing Operation Controls Were Established

The TMOP program contractor designed controls, including automated controls and pharmacist intervention, to ensure beneficiaries received only necessary pharmaceuticals. During CY 2012, the TMOP program contractor denied 2 million prescriptions of the 19.6 million prescriptions received. The controls ensured that prescriptions were denied for multiple reasons including:

- prescriptions were not yet eligible to be refilled,
- prescriptions had missing or invalid information,
- pharmaceuticals were not covered by the TRICARE program,
- patients were not eligible to participate in the TRICARE program,
- expired prescriptions,
- interaction of prescribed medications could have been harmful, and
- duplicate claims or adequate supply of the drug.

Ian Duncan, Nikhil Khandelwal, and Patricia Murphy, "Comparing medication wastage by fill quantity and fulfillment channel," American Journal of Pharmacy Benefits. 4,5 (2012)

⁶ Pharmacy Benefit Management Institute 2012-2013 Prescription Drug Benefit Cost and Plan Design Report.

Certain automated controls are dependent upon the availability and accuracy of two government systems; DEERS and the Pharmacy Data Transaction Service (PDTS). The TMOP program contractor accesses DEERS while processing each prescription to determine beneficiary eligibility to participate in the program. In addition, the TMOP program contractor accesses PDTS to perform a drug utilization review for beneficiary safety. PDTS allows the contractor to identify a beneficiary's current pharmaceutical profile, including prescriptions filled by the TMOP program, MTFs, or retail pharmacy claims that are paid by TRICARE. The TMOP program contractor uses this profile to analyze prescriptions clinically for any potential adverse drug interactions. In addition, the TMOP program contractor reviews prescriptions to identify multiple prescriptions for the same health condition or for the same pharmaceutical of varying strengths, which indicates a possibility that a beneficiary's current prescription has been modified. If the TMOP program contractor's system identifies a potential problem, a real-time alert is issued to the dispensing pharmacist to prevent drug-related adverse events. The pharmacist would review the prescription change, contact the prescribing physician to resolve any questions regarding safety or medication therapy concerns, and discontinue any unnecessary prescriptions from the beneficiary's profile.

The Auto Refill program also had controls to limit waste. This program allows beneficiaries to choose automatic shipment of their refills with the option to enroll any or all of their prescriptions. The Auto Refill program was intended for maintenance medications and not for medications taken occasionally or as needed; prescribers could allow refills for up to 1 year.⁷ Upon expiration, a new prescription must be sent to the TMOP program contractor to continue receiving the pharmaceutical. The TMOP program contractor would notify the beneficiary of the upcoming refill action based on their record. Unless the beneficiary requested a cancellation, the contractor would process the refills based on when their previous fill would run out. If the prescription was not needed at that time, the beneficiary could cancel or postpone the refill before processing. According to TMOP program contractor personnel, the beneficiary could also remove prescriptions from the Auto Refill program at any time by telephone or through the TMOP program contractor website. Additionally, beneficiaries could remove their prescriptions from the TMOP program and obtain remaining refills at a retail or MTF pharmacy. Like all refill options, it was the beneficiaries' responsibility to manage participation in the Auto Refill program. According to the TMOP program contractor, automatic refills represented 35 percent of the 16.9 million CY 2012 mail order prescriptions filled.

⁷ Refills for certain controlled substances were prohibited or limited to 6 months under the Controlled Substances Act.

Low Prescription Error Rates

According to the TMOP program contractor, prescriptions filled through the TMOP program were 99.997 percent free of clinical errors, such as shipping the incorrect pharmaceuticals, while retail pharmacy programs were 98.5 percent error free. The TMOP program contractor attributed the higher effectiveness, in part, to automated filling of high volume pharmaceuticals. Specifically, the TMOP program contractor filled 80 percent of DoD mail order prescriptions through automation and only 20 percent manually. Prescriptions filled by automation encountered various control mechanisms to ensure the medications were filled accurately and efficiently; therefore, reducing the potential of wasted pharmaceuticals and adverse health risks due to beneficiaries taking incorrect pharmaceuticals.

Low Percentage of Returned Pharmaceuticals

The TMOP program contractor received a very small percentage of mail order pharmaceuticals in returns, giving further indication that the controls over mail order prescriptions were working as intended. The TMOP program contractor shipped 16.9 million prescriptions received in CY 2012 to TRICARE beneficiaries. Of the 16.9 million prescriptions shipped, the TMOP program contractor processed approximately 24,000 returns. However, pharmaceuticals for only approximately 14,000 prescriptions, or 0.08 percent, were returned as undeliverable and had to be disposed. The majority of initial returns resulted from incorrect addresses provided by the beneficiary.

Quarterly Surveys Showed Beneficiary Satisfaction

Quarterly telephonic surveys conducted by a third-party contractor on behalf of DoD showed that beneficiaries were consistently satisfied with the mail order services provided by the TMOP program contractor. From December 2009 to November 2012, the number of respondents who answered that they were somewhat, very, or completely satisfied averaged 96 percent.

Cost Savings and Potentially Reduced Health Risks

The TMOP program overall was more cost efficient than the retail pharmacy method of obtaining pharmaceuticals. In addition, the TMOP program contractor had adequate controls in place designed to identify and deny prescriptions that were ineligible or unnecessary. The TMOP program also has features advantageous for beneficiary health. For example, the TMOP program contractor's prescription accuracy rate exceeded the retail industry average, reducing the risk of adverse health outcomes to beneficiaries as

a result of taking the wrong pharmaceuticals. Another benefit of the TMOP program was the automatic refill and shipment option designed to ensure beneficiaries' medications were available on time without lapse. We believe that the overwhelming use of mail order pharmacy plans by employers combined with the availability of mail order options at major retail chains is an acknowledgement of the value added by mail order pharmacy programs. Therefore, the TMOP program overall provided cost savings to DoD while potentially preventing health risks to DoD beneficiaries.

Review of Internal Controls

The internal controls relative to the selected aspects of the TMOP program were generally effective as they applied to the audit objective.

Audit Scope and Methodology

We conducted this performance audit from December 2012 through July 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Congressional members, who requested the audit, had questions on the effectiveness of patients utilizing their medications or what changes would ensure patients were taking their medications. However, we responded separately in January 2013 that we would not review patient utilization of their medications.

To obtain background information on TMOP and history of the mail order pharmacy benefit, we met with representatives from TMA and reviewed historical information. We reviewed the TRICARE Pharmacy contract to determine the contractor's requirements for administering the TMOP program as well as information provided to beneficiaries, including the TRICARE Pharmacy Handbook and information on the TRICARE and TMOP program contractor websites, and used the results to compare TMOP to standard U.S. pharmacy industry policies and practices. To identify standard industry policies and practices, we conducted teleconferences with and obtained information from two retail pharmacy trade associations; reviewed peer-reviewed industry research; and reviewed an industry survey of trends in employer-provided pharmacy benefit programs.

To obtain information on the cost analysis of the TMOP program we met with the Chief of the TMA Pharmaceutical and Operations Directorate and his staff, and representatives of

the DoD Pharmacoeconomic Center. We reviewed and analyzed the latest completed cost analysis that covered the FY 2012 third quarter to determine which costs were included and if the TMOP program was an efficient way to deliver prescription drugs to TRICARE beneficiaries. We also reviewed the TMOP contract line item number payouts from November 2009 through December 2012 to verify the costs considered in the cost analysis were accurate and complete. We reviewed Federal and DoD regulations to determine if cost analyses were required before entering into a contract and during the life of a contract. To gain an understanding of the process for returning pharmaceuticals, we interviewed personnel from TRICARE and searched the Defense Supply Center Philadelphia web-site for information on the Pharmaceutical Reverse Distribution Program. We also reviewed the TMOP contract and the Pharmaceutical Reverse Distribution contract for cost information. From interviews with TMA personnel, we were able to determine the payment and credit process associated with the TMOP program contractor.

To determine whether adequate dispensing controls were in place, we reviewed controls at the TMOP program contractor facility in Tempe, Arizona. We conducted a site visit at the TMOP program contractor's facility to observe procedures used to process prescriptions from receipt of the prescription to shipment. We interviewed TMOP program contractor and TMA personnel. We obtained and analyzed copies of standard operating procedures and process overviews. We reviewed CY 2012 statistics on prescriptions received, filled, denied, and returned; however, we did not audit the quantities or dollar amounts listed in the reports and cannot attest to their accuracy. In addition, we reviewed the reasons provided for prescriptions denied and returned in CY 2012.

Use of Computer-Processed Data

We relied on summaries of computer-processed data provided by the TMOP program contractor, to include number of prescriptions received, dispensed, denied, and returned. The TMOP contractor's proprietary information system relied primarily on PDTS for controls over processing prescriptions. We also relied on PDTS data that formed the basis for the TMA cost analyses associated with the efficiency of the TMOP program. To test the reliability of PDTS data, we statistically selected an internal controls sample of 45 filled prescriptions from PDTS and compared the information with images of the original prescriptions. We found no inconsistencies between the PDTS data and the source documentation, and therefore conclude, with 90 percent confidence, that the error rate is under 5 percent. Based on the results of our sample, and our positive conclusions regarding controls over processing prescriptions, we determined the summary data we obtained was sufficiently reliable to accomplish our audit objective.

Prior Audit Coverage

During the last 5 years, the Government Accountability Office issued one report, referenced on page 2 of this report, discussing the DoD Pharmacy Program. Unrestricted Government Accountability Office reports can be accessed over the Internet at http://www.gao.gov.

You can obtain information about the Department of Defense Office of Inspector General from DoD Directive 5106.01, "Inspector General of the Department of Defense (IG DoD)," April 20, 2012; DoD Instruction 7600.02, "Audit Policies," April 27, 2007; and DoD Instruction 7050.3, "Access to Records and Information by the Inspector General, Department of Defense," April 24, 2000. Our website is www.dodig.mil.

We appreciate the courtesies extended to the staff. If you have any questions, please contact me at (703) 604-8866 (DSN 664-8866).

Alice F. Carey

alice Harry

Assistant Inspector General

Contract Management and Payments

Enclosures

Congress of the United States Washington, DC 20515

August 3, 2012

Ms. Lynne M. Halbrooks Acting Inspector General Department of Defense 4800 Mark Center Drive Alexandria, VA 22350-1500

Dear Ms. Halbrooks:

We write to request the Department of Defense Office of Inspector General (OIG) conduct an audit of the extent to which policies and programs that encourage the utilization of the TRICARE national mail order pharmacy program may contribute to pharmaceutical waste and unnecessary expenditures for the Department of Defense.

For years, the TRICARE pharmacy co-payment structure has encouraged the use of mail order. Co-payments changes effective October 1, 2011 provide greater incentives for beneficiaries to obtain prescription drugs from the TRICARE Mail Order Pharmacy (TMOP). and the FY2013 National Defense Authorization Act passed by the House on May 18, 2012 provides further incentives.

Given these efforts to increase the use of mail order in the TRICARE pharmacy program, we would like to better understand what controls are in place to ensure the TMOP is providing prescription drugs to beneficiaries in the most efficient and cost effective manner. Specifically, we would like to understand:

- What controls are in place to ensure patients do not receive medications which they no longer need?
- What processes exist to halt the shipment of medication when type of medication, dosage, strength or other changes are made by a patient's physician?
- Are TRICARE beneficiaries provided an opportunity to opt-out of automatic refill programs?
- Is higher utilization of mail order resulting in waste (in volume, prescription, and patient population) and increased health care costs for the Department of Defense?

In addition, how effectively are patients utilizing their medications? How is TRICARE measuring adherence? Lastly, what policy recommendations would your organization make to ensure patients are taking the medications they are sent? We request that you conduct this audit and report on its work within 180 days of the date of this letter. Further, we request that you consult with relevant stakeholders, such as the TRICARE pharmacy benefit manager, beneficiaries, pharmacies and others as deemed necessary.

Thank you for your cooperation and attention to this important matter. If you or your staff has any questions regarding this matter, please contact either Nora Todd (Rep. Michaud) at 202/225-6306 or Ray Celeste, Jr. (Rep. Jones) 202/226-5241.

Sincerely,

Michael H. Michaud

Member of Congress

Larry Kissell

Member of Congress

Martha Roby Member of Congress

Member of Congress

Member of Congress

Renee(HImers

Member of Congress

Member of Congress

Austin Scott

Member of Congress

United States Senate

WASHINGTON, DC 20510

September 28, 2012

Ms. Lynne M. Halbrooks Acting Inspector General Department of Defense 4800 Mark Center Drive Alexandria, VA 22350-1500

Dear Ms. Halbrooks:

We write to request that your office conduct an audit of the TRICARE Mail Order Pharmacy (TMOP) program to determine whether policies that encourage mail order prescription utilization may contribute to pharmaceutical waste and unnecessary expenditures for the Department of Defense (DOD).

For years, TRICARE has encouraged the use of mail order pharmacy services. TRICARE's current prescription drug copayment structure provides greater financial incentives for beneficiaries to obtain prescription drugs from TMOP by establishing TMOP copayment levels that are significantly below copayment levels for traditional retailers.

Given these efforts to increase mail order utilization, we would like to better understand what controls are in place to ensure TMOP is providing prescription drugs to beneficiaries in the most efficient and cost-effective manner. Specifically, we would like to understand:

- 1) Is the increased utilization of mail order resulting in waste (in volume, prescription, and patient population) and increased health care costs for the Department of Defense?
- 2) What controls are in place to ensure patients are utilizing their medications and do not receive medications they no longer need?
- 3) What processes exist to halt the shipment of medication when type of medication, dosage, strength or other changes are made by a patient's physician?
- 4) Are TRICARE beneficiaries provided an opportunity to opt-out of automatic refill programs?

An expeditious audit by your office - that includes consultation with relevant stakeholders - will greatly inform Congress and DOD leadership as we continue our efforts to pursue TRICARE policies that ensure the best medical care for patients and best value for the American taxpayer.

Thank you for your consideration.

Sincerely,

United States Senator

Inited States Senator

United States Senator

Whistleblower Protection

U.S. DEPARTMENT OF DEFENSE

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